K082393

Registration No. 1034196

510(k) Summary

SEP 1 1 2008

Applicant Information

Date prepared:	18 August 2008
Name:	Unilens Corp., USA
Address:	10431 72nd Street, North Largo, FL 33777
Contact person:	Alan J. Frazer Director of Quality Assurance
Phone number:	(727) 544-2531
Fax number:	(727) 545-1883

Device Information

Device classification:	Class II
Classification number:	LPL
Classification name:	Lenses, Soft Contact, Daily Wear
Trade name:	C-VUE® Advanced™ (hioxifilcon D) Soft (hydrophilic) Contact Lens

Equivalent device

The C-VUE® Advanced™ (hioxifilcon D) Soft (hydrophilic) Contact Lens for Daily Wear is substantially equivalent to the predicate device identified below in terms of intended use and design.

Predicate device:

C-VUE® Toric Multifocal (methafilcon A) Soft (hydrophilic) Contact Lens; and
Benz-G 4X 54% (hioxifilcon D) Lathed Sphere and Toric Lenses

Device description

CVUE ADVANCED (hioxifilcon D) soft contact lenses are semi-scleral flexible shells which cover the cornea and may cover a portion of the adjacent sclera and are available as aspheric single vision, multifocal, toric, or toric multifocal designs. Torics have a toroidal posterior optic zone, and multifocals have the most plus power is in the center of the lens, with the power progressively becoming more minus towards the periphery. All lenses share a base curve with a flattened peripheral curve which approximates the curvature of the sclera. The lens material, (hioxifilcon D), is a non-ionic copolymer of 2-hydroxyethyl methacrylate (2-HEMA) and 2, 3-dihydroxypropyl methacrylate (Glycerol Methacrylate, GMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA). It consists of 46% hioxifilcon D and 54% water by weight when immersed in normal buffered saline solution. The lens is

available with or without a blue visibility handling tint, phthalocyanato (2) - (copper).

The CVUE ADVANCED (hioxifilcon D) soft contact lens is a hemispherical shell of the following dimensions:

Chord diameter:	12.5 to 17.0mm
Center thickness:	0.13 to 0.73; varies with power
Base curve:	7.0 to 10.5mm
Powers:	-20.00 to +20.00 diopters
ADD powers (multifocal):	Up to +3.00 diopters
Cylinder (toric):	Up to 4.00 diopters
Axis (toric):	0° to 180° in 1° steps
Optical zone diameters:	5.0 to 10.0mm

The physical/optical properties of the lens are:

Refractive Index	1.408 (hydrated)
Light Transmission – tinted	greater than 90%
Water Content	54%
Specific Gravity	1.299 (dry)
Oxygen Permeability (Dk Value)	23 x 10-11 Fatt Units (cm2/sec) (ml O2/ml x mm Hg @ 35°C), ANSI Z80.20:2004 upgraded polarographic method corrected for boundary-layer and edge effects

Intended Use (Indications)

The CVUE ADVANCED (hioxifilcon D) Single Vision Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes. The lens may be worn by persons who require up to 3.00 Diopters of add and who exhibit astigmatism of up to 0.75 Diopters that does not interfere with visual acuity.

The CVUE ADVANCED (hioxifilcon D) Toric and Multifocal Toric Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), presbyopia and astigmatism up to 4.00 diopters in aphakic and/or not-aphakic persons with non-diseased eyes.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfection system.

Substantial equivalence

The CVUE ADVANCED (hioxifilcon D) Single Vision Contact Lenses will be manufactured according to specified process controls and a quality management system currently in place. The device will undergo manufacturing, packaging and sterilization procedures similar to devices currently manufactured, marketed and

distributed by Unilens Corp., USA. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the device is equivalent to the BENZ-G 4X (hioxifilcon D), 510(k) K062854. Being similar with respect to indications for use, materials, physical construction and safety and effectiveness to the predicate device, this meets the requirements per section 510(k) of the act regarding substantial equivalence and does not raise different questions of safety and effectiveness than the predicate devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 1 2008

Unilens Corp.,USA
Alan J. Frazer
Director of Quality Assurance
10431 72nd Street, North
Largo FL 33777

Re: K082393

Trade/Device Name: C-VUE® Advanced™ (hioxifilcon D) Soft (hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: August 18, 2008
Received: August 19, 2008

Dear Mr. Frazer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082393

Device Name: C-Vue® Advanced™ (hioxifiocon D) soft (hydrophilic) contact lenses

Indications for Use:

The CVUE ADVANCED (hioxifilcon D) Single Vision and Multifocal Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) and presbyopia in aphakic and/or not-aphakic persons with non-diseased eyes. The lens may be worn by persons who require up to 3.00 Diopters of add and who exhibit astigmatism of up to 0.75 Diopters that does not interfere with visual acuity.

The CVUE ADVANCED (hioxifilcon D) Toric and Multifocal Toric Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), presbyopia and astigmatism up to 4.00 diopters in aphakic and/or not-aphakic persons with non-diseased eyes.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K082393

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